

CLINICAL SUPPLY CHAIN eLEARNING COURSE

Lesson 1: Overview of Clinical Trials

- Overview of Clinical Development Phases (i.e. Preclinical, Phase 1 - Phase 4, Compassionate Use, Investigator-Initiated Trials)
- Trial Types (Single Blind, Double Blind, Open Label, Maintaining the Blind)
- Trial Design Considerations
- Role of Clinical Supply Chain in a Clinical Trial
- Overview of Clinical Trial Terms
- Critical Clinical Supply Chain Milestones (i.e. First Patient In, First Patient Dosed, etc.)

Lesson 2: Enrollment Forecasting and Clinical Supply Chain's Role in Managing Inventory

- Planning for the Supply of a Clinical Trial (Data Driven Decisions, Open Communications, Proactive Preparations)
- Manufacturing (Active Pharmaceutical Ingredient, Drug Product Manufacturing, Active Substances)
- Packaging / Labeling (Process and Design, Regulations)
- Storage / Distribution (Temperature, Storage Conditions, Special Considerations, Depots, Quality Release)
- Close Out Considerations

Lesson 3: Key Skills for a Career in Clinical Trial Supply

- Project Management Skills
- Handling Restrictions and Variables
- Problem Solving Skills
- Communication Skills
- Versatility and Resourcefulness
- Preparing for the Unexpected
- Attention to Detail
- Multi-Cultural Awareness
- Other Success Factors